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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,957	01/07/2002	Chiaki Saitoh	506.41066X00	6269
20457	7590	07/17/2003		
ANTONELLI, TERRY, STOUT & KRAUS, LLP 1300 NORTH SEVENTEENTH STREET SUITE 1800 ARLINGTON, VA 22209-9889			EXAMINER	
			SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 07/17/2003				

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 10/019,957	Applicant(s) Saitoh et al.
Examiner Sandra Saucier	Art Unit 1651

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on May 20, 2003.

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-81 is/are pending in the application.

4a) Of the above, claim(s) 1-11 and 46-53 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 12-45 and 54-81 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
- Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- Notice of Informal Patent Application (PTO-152)
- Other: \_\_\_\_\_

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#### DETAILED ACTION

Claims 1–81 are pending. Claims 12–45 and 54–81 are considered on the merits. Claims 1–11, 46–53 are withdrawn from consideration as being drawn to a non-elected invention.

#### *Election/Restriction*

Claims 1–11 and 46–53 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made without traverse in Paper No. 8.

#### *Information Disclosure Statement*

The listing of the references on PTO 1449 is incomplete. A proper citation includes AUTHOR, TITLE, JOURNAL, VOLUME, NUMBER, INCLUSIVE PAGES, (month), YEAR. The citation is missing the author and title of the article.

MPEP 37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

The reference labeled AU lacks the year of publication. Please submit a new PTO 1449 which has this information for Thomas [AU].

#### *Claim Rejections – 35 USC § 112*

INDEFINITE

Claims 12–45 and 54–81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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It is uncertain whether the microbe which catalyzes the 13-hydroxylation is a different or may be the same microbe which performs the  $\beta$ -oxidation. Thus, claims 12 and 28 may be interpreted to use the same species of organism for the first and second organism.

There is no antecedent basis for the recitation of "the first" and "the second microorganism" in claims 12 and 28.

Claims 12, 13, 25, 26, 28, 29, 41, 42, 64, 65, 77, 78 have parenthetical inclusions. It is unclear if applicants seek to expand or further limit the elements of the claim followed by these inclusions. Please do not use parenthesis in the claims.

#### DEPOSIT

Claims 20, 24, 36, 40, 59, 63, 72 and 76 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism.

The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record

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over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

If the deposit is not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria, assurance must be provided to the effect that:

- (1) during the pendency of the application, access to the cultures will be made available to one determined by the Commissioner to be entitled thereto;
- (2) any restrictions on availability of the deposits to the public will be irrevocably removed upon the granting of a patent;
- (3) the deposits will be maintained for a term of at least of 30 years from the date of deposit and at least 5 years after the last request for the material;
- (4) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (5) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

Assurance may be provided in the form of an affidavit, declaration or averment under oath or by a statement of the attorney of record over her or his signature and registration number.

The specification must also state the date of deposit, the number granted by the depository and the name and address of the depository. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

**It is unclear if the specific strains of the microbes of the claims have been obtained from a public depository or if they are applicants' own isolates. Please clarify the status of the availability of each microbe in the rejected claims.**

#### *Claim Rejections – 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

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to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-17, 21-25, 27-33, 37-41, 43-45, 54-56, 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Endrizzi *et al.* [AW] in combination with Hudson *et al.* [U] or Fox *et al.* [V].

The claims are directed to a two step process for the production of  $\delta$  lactone by reacting an (n-6) unsaturated fatty acid with 10 or more carbons in a linear chain, with a microbe to yield a corresponding (n-5) hydroxy fatty acid with saturation in the n-6 position. Then the hydroxylated fatty acid is converted via a microbial beta oxidation reaction which sequentially removes carbons in pairs from the hydroxylated fatty acid which then forms a 6 membered internal lactone.

The references are relied upon as explained below.

Hudson *et al.* disclose that *Enterococcus faecalis* and *Streptococcus bovis* convert linoleic acid to 13-hydroxy-9-octadecenoic acid.

Fox *et al.* disclose that *Leptomyces lacteus* convert linoleic acid to 13-hydroxy-octadecamonoenoic acid.

Endrizzi *et al.* disclose that  $\beta$ -oxidation of fatty acids with the hydroxyl group on an odd carbon is possible, and that yeast, such as from the genera *Candida*, *Pichia*, *Hansenula* and others possess a peroxisomal system which performs this reaction (page 309-311). Further, the formation of lactones from hydroxy acids can be done with acidification of the medium. In Table 1, delta lactones, specifically, can be formed from fatty acids by yeasts and fungi such as *Saccharomyces cerevisiae* or *Kluveromyces lactis* or *Pichia etchellsii*. These lactones are used in the food industry.

The substitution of a 13-hydroxy-octadecenoic acid produced by the

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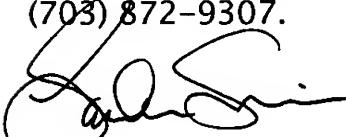
methods of Hudson *et al.* or Fox *et al.* which produce a 13-hydroxy-octadecenoic acid by use of *E. faecalis* or *S. bovis* or *L. lacteus* from linoleic, as a substrate to produce delta lactone by *Saccharomyces cerevisiae* or *Kluveromyces lactis* or *Pichia etchellsii* or a yeast from the genus *Zygosaccharomyces*, which microbes have also been classified as *Saccharomyces* (see ATCC 36947) in the method of Endrizzi *et al.* would have been obvious at the time the invention was made. Endrizzi *et al.* teach that yeast can perform beta oxidation on hydroxylated fatty acids, which beta oxidized fatty acids, particular species of yeasts are specifically taught by Endrizzi *et al.* to form delta lactones.

Claims 18-20, 26 34-36, 42, 57-66 and 70-81 are free of the art.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting compound as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier  
Primary Examiner  
Art Unit 1651  
July 14, 2003